



Tort Liability and Vaccine Manufacturers

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Tort Liability and Vaccine Manufacturers
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In 1902, Congress passed the Biologics Act. Reenacted in 1944, the Act remains the primary piece of legislation regulating the use of human biological products, including serums, toxins, antitoxins, vaccines, and blood and blood products. Although the Act gives the Bureau of Biologics (as it is currently known) complete power to regulate these products, it never answers the central question whether FDA approval of vaccines immunizes their manufacturers from tort liability. Since the amount of liability a vaccine company faces directly affects its willingness to develop and market such products, the answer to this question will affect millions of lives. Furthermore, this issue will only become more hotly contested in the future as AIDS vaccines, whose side effects cannot fully be known, are developed. A summary of the landmark decision, Reyes v. Wyeth Laboratories (1974), will provide an interesting platform from which to launch a discussion of this important subject.

In Reyes the fifth circuit expanded the scope of liability for manufacturers of human vaccines. In May, 1970, the plaintiff in that case, Anita Reyes, had become paralyzed after having been fed by eye-dropper oral polio vaccine manufactured by the defendant drug company. The Court began its opinion by dividing human vaccines into two categories—those unreasonably dangerous per se and those unreasonably dangerous as marketed.⁷ Marketing of a vaccine in the former group was totally prohibited because, in the court's opinion, the product was not net socially beneficial. A vaccine in the latter group, however, could be marketed as long as accompanied by a proper warning of the possible side effects of using the drug.

Believing that the polio vaccine in question clearly belonged in the second group (the chance of contracting polio from an attempted immunization was one in a million), the Court proceeded to question the sufficiency of the defendant's warning. Since the plaintiff had received the drug from a public health nurse at a

local clinic, the Court determined that the vaccine was not administered as a prescription drug. As a result, the normal working rule that a drug manufacturer owes a duty to warn of any possible dangers inherent in use of its products only to the prescribing physician was found inapplicable to the present situation.

The Reyes court then followed the rule of an earlier case, Davis v. Wyeth Laboratories 399 F.2d 121, in which the ninth circuit held that absent the intervention of an individualized medical judgment between the manufacturer of a prescription drug and the ultimate consumer, it is the responsibility of the manufacturer to see that warnings reach the consumer, either by giving warning itself or by obligating the purchaser to give warning. Although the defendant in the Reyes case had included a package circular with every vial of its vaccine, the Court found this warning insufficient to provide notice to the vaccinees of the dangers posed by use of the drug. The Court further noted that the defendant could not take advantage of the prescription drug exception to escape from liability since it was clearly foreseeable to the manufacturer that its vaccine could be administered by a public nurse in a local clinic without any physician present. In fact, a Wyeth representative had testified during the trial that it was common knowledge among vaccine manufacturers that their drugs were dispensed in this manner.

After the jury determined that the polio vaccine caused the plaintiff's injury, the burden shifted to the defendant to rebut the presumption that a warning would have changed the plaintiffs decision to take the vaccine, thus preventing the injury. In judging this question, the Court resorted to an objective standard by asking if the reasonable defendant would have made a different decision if presented with the proper safety information. The Court concluded that Wyeth failed to meet its burden citing as justification for this judgment the

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manufacturer's failure to inform the plaintiff of a way to reduce the risk posed by use of its vaccine.

The driving force behind the Court's opinion was its belief that vaccinees have a liberty interest at stake, which it defined as the right of the individual to choose and control what risk he will take. Sometimes, the Court conceded, the countervailing societal and individual interest will be so overwhelming that the manufacturer will not be required to provide sufficient information for the vaccinee to make an informed judgment. But in the present case, the Court maintained, the possible injury resulting from use of defendant's vaccine was serious enough that the individual could rationally have refused it. In other words, the individual had a true choice judgment that the manufacturer should have respected.

The Court then concluded by dismissing arguments made by the defendant. To the defendant's complaint that an effective warning would have to be so scientific and detailed that it would deter people from seeking inoculation against polio, the Court conclusorily stated that a policy of warning plaintiffs of the risks inherent in vaccination could be compatible with a public policy favoring inoculation. The Court was somewhat more solicitous of the drug company's argument that Texas's requirement that all of its schoolchildren receive immunization against polio rendered the warnings irrelevant. But the Court also rejected this argument. Although the children may not avoid inoculation, the Court reasoned, they still may choose the method of receiving it. In this case, the court noted that the plaintiff could have opted for inoculation from killed-virus Salk vaccine in lieu of the oral polio vaccine manufactured by the defendant.

Although it is easy to sympathize with the outcome of Reyes the decision is seriously flawed by the court's failure to debate, let alone justify, its institutional competence to decide issues of drug law. Admittedly, courts rarely do question

their competence to hear a case but, as scientific knowledge progresses, it seems they should. More importantly, the Reyes court never debates the merits of imposing liability on a manufacturer whose product and warning had been approved by the Food and Drug Administration (FDA). Since the Court fails to note the Agency's role, the typical reader, unaware that all biologics must receive such approval prior to marketing and distribution, can be forgiven for believing that the Court had reined in a greedy, socially unconcerned corporation. Unfortunately, the reality was otherwise.

Although Wyeth Laboratories had complied in good faith with all relevant federal regulations in a highly-regulated industry, the Reyes court afforded the vaccinee even greater protection. The decision effectively placed on vaccine manufacturers the burden of proving that warnings contained on their vaccines are both necessary and appropriate. And, even if a company is particularly prudent in performing its duties and holds its products to an even higher safety standard than that mandated by the FDA, the Reyes decision allows a court to hold it to a still higher one.

There are many reasons, some ideological and some political, that can explain Congress's refusal to statutorily overturn the Reyes decision until twelve years after it was decided. Its failure to do so was possibly a tacit acceptance of the Court's view that the FDA, and all government agencies for that matter, sometimes make decisions that cause injury. Allowing recourse to the court system protects the public from the occasional failures of these administrative agencies. (Of course, it is not readily apparent why manufacturers should pay for mistakes made by organs of the government). It is also possible that Congress let the Reyes decision stand because it believed that manufacturers should insure individuals against injuries resulting from use of their vaccines. Under this view,

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it is not relevant whether the FDA determined the negligence standard properly since defendants are held strictly liable for their actions.

Alternatively, Congress's decision to allow tort liability for manufacturers possibly evidenced a desire to avoid blame for its role in harming the plaintiff. After all, Congress as represented by the FDA could have taken measures to prevent the plaintiff's injury. It could have required the warning demanded by the Reves court prior to the injury. Or it could have required an even more stringent one. Or it could never have approved the vaccine in the first place. The public, however, probably viewed the Reyes decision as a moral condemnation of the defendant. The Court's decision provided Congress as represented by the FDA with at least a partial shield against public criticism.

Regardless of the motive underlying Congress's refusal to immediately overturn Reyes the decision had disastrous consequences for the drug industry and, inevitably, for the health of the American public. By permitting a court to blame the drug manufacturer instead of the FDA, Congress never asked whether anyone should be blamed for injuries that result from use of FDA-approved vaccines. Obviously, moral and economic arguments can be made on both sides of the question. Certainly, a drug manufacturer and the government can assert with some degree of conviction that if a FDA-approved vaccine is accompanied by an FDA-approved label, then an individual choosing to use the vaccine assumes the risk. An individual seeking protection against these injuries, they can argue, should self-insure.

Many scholars criticize this view. They argue that a healthy individual, injured by use of a drug company's product, should be made whole by a monetary award. But this argument rests on a false conception of health. Although an individual may outwardly appear healthy, that individual's future is fraught with risk. All individuals carry within them a potential, albeit an

extremely small one in most cases, for contracting almost any disease. When an individual chooses to inoculate himself or herself against one of these potentials, he or she is merely trading risks. That the government or industry should pay when individuals gamble and lose is not the clearcut proposition that adherents of liability contend.

The argument against insurance does become a bit more complicated when government mandates inoculation. Even then, however, it can be justified by the strong public policy of preventing the spread of infectious illnesses. The individual is forced to relinquish control over the level of risk he or she would choose, but, people are asked to make sacrifices for the good of society every day. Obvious examples are a progressive income tax and use of all taxpayers' money to fund public education, despite the reality that many citizens benefit only indirectly from government provision of this service.

Admittedly, compromise in pursuit of the public interest seems more difficult when it involves forcing an individual to take an action that may cost him his life. Society, however, is continually making compromises that lead to loss of life. Permitting automobile drivers to travel at a speed of 55 miles per hour and allowing people over the age of twenty-one to drink alcohol provide two examples of this proposition. Studies clearly have shown that slower driving and less drinking lead to fewer deaths and injuries. Yet there is no movement towards making these changes. In fact, just the opposite is true. Obviously, society has decided that, at some point, human life is not worth saving. Beyond some level of inconvenience and expense, we are all unwilling to compromise in the interest of preserving life.

In the realm of biologics, compromise should seem easier. Unlike the driving and drinking examples above, where lives are balanced against convenience and cost, the debate concerning tort liability for vaccine

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manufacturers weighs lives against other lives. So a sacrifice that costs lives also save lives. Instead of taking comfort in those saved, however, we focus on the resulting deaths even though they are invariably fewer in number. Somehow, random but definite deaths today seem far worse than random but definite deaths tomorrow. Also, vaccine-related fatalities seem bizarre and carry with them an aura of malpractice whereas those resulting from disease seem natural and inevitable. Unfortunately, our intellect is limited by our inability to view the world statistically. Unlike a death caused by disease, we can pinpoint the cause of a vaccine-related injury. In our despair at this death, we strike out at the vaccine's manufacturer, seemingly forgetting the lives saved by the very same product.

The previous discussion, of course, is purely academic. One must never forget that the FDA, like all other government institutions, can maintain its legitimacy only so long as its decisions are ratified by society. So even if it seems rational that the FDA approve all vaccines that are net socially beneficial, they certainly will not. Although a particular vaccine might save 50 lives, the FDA probably would not approve it if it would cause 45 deaths. Similarly, even if the logic underpinning insurance for vaccine victims is at best questionable, it will be provided. Current societal values demand no less. In this light, the real questions are how much insurance and who will pay for this insurance.

The debate about how much insurance to provide is in reality nothing more than the age-old debate concerning the proper standard of liability. In recent years, however, the traditional debate between strict liability and negligence has been completely undermined. It is now commonly recognized that the difference between these standards is merely one of degree, not kind. As negligence is defined in broader terms, it becomes increasingly difficult to distinguish it from

strict liability. In the modern era, therefore, we are no longer presented with a choice between negligence or strict liability, but between more or less liability.

Proponents of higher liability argue that increasing the exposure of vaccine manufacturers will give these companies incentive to make their products safer. The less in damages awards that these companies pay, the argument continues, the lower the prices they will charge for their drugs and the larger their market share will be. Unfortunately, this argument fails if the initial increase in the price of the drug results in its removal from the market. This may happen if its manufacturers are unable to approximate the amount of tort damages they will have to pay and, accordingly, are uncertain at what price to set the vaccine. Alternatively, the drug may remain on the market but its price may be so high that only the wealthiest or those with the best health care plans will be able to afford it. If the need for the drug is strong enough, then the public will demand that government subsidize its use. In the end, there will be little substantive difference between an insurance system funded by the drug industry and one paid for by the government.

In response to this argument, critics often assert that the profits of drug companies are so great that even if they are forced to assume liability for all injuries caused by their vaccines, they surely can afford this additional cost of doing business. But these critics miss a basic point. Private drug companies still may be able to attain a profit, possibly even a handsome one, by producing a vaccine for whose harmful effects they will bear liability. But will they produce such a vaccine? Instead these companies may choose to improve the products they presently produce. Or maybe they will decide to develop drugs in areas presenting less risk than that of biologics. A large drug company or its owner may even choose to expand into other industries in which the potential profits are greater.

It is thus dear that a standard of care must be chosen that will provide an intelligent mix of protection for the vaccinee and incentive for the manufacturer. A standard chosen that is too favorable to either interest will result in a higher number of deaths than necessary. Furthermore, the FDA is certainly the organization best suited to setting such a standard. One of the primary rationales of administrative law is the desirability and necessity of having judges with the proper expertise making the decisions in areas of great complexity. If this rationale justifies the legal functions of all of the departments of the executive branch, it applies with special force in the area of biologics.

It truly seems doubtful that a courtroom judge possesses the experience to understand the careful policy compromises engaged in by the FDA every time it approves a warning label attached to a vaccine. Similarly, it is equally unlikely that a judge has the background necessary to understand the scientific studies that contribute to an FDA decision to approve a vaccine. The FDA's Bureau of Biologics, on the other hand, has a special tradition of employing accomplished scientists dating back to the period when the Bureau was a division within the National Institutes of Health (NIH). In this light, it seems highly improbable that a judge is as well equipped as an FDA official to make an intelligent compromise between the safety of biologics and the deterrence of their manufacturers.

Of course, an argument that the FDA should have sole jurisdiction over liability in the biologics area is not tantamount to a belief that the agency is perfect. Clearly, the FDA, like all other bureaucracies, may be inefficient in certain respects. With only about eight thousand workers nationwide and a limited budget, it cannot be as responsive as some citizens would like. But the overcrowded court system does not provide a solution to any of the FDA's problems. Since a court can only operate after a case or controversy has arisen, it is limited even if its judges somehow have the knowledge necessary to render an intelligent decision.

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Unlike the determinations of a federal administrative agency, court decisions cannot provide notice to a manufacturer that will enable it to make informed business decisions. And, if these companies face uncertain liability in tort, they will be less willing to assume risk. Correspondingly, the development of much-needed drugs will be impeded.

There are still more reasons to defer to the FDA in the biologics area. With one administrative agency making all decisions concerning negligence, like cases are more likely to be treated in the same manner. Uniformity of decision-making is less likely when decisions are made by judges possessing different levels of knowledge sitting in different circuits. In addition, the FDA has ample statutory authority to insure that the standards it requires are met. It not only can inspect any lot of vaccine it chooses, but also can inspect at all reasonable hours any manufacturing plant. Furthermore, the reputation it has earned, especially when compared to other federal agencies like HUD and the EPA, shows that its standards have gained acceptance by the public. And, if the FDA does begin to make mistakes, public criticism and congressional inquiries will assuredly provide ample impetus for its improvement.

Once the FDA has set the standard for a vaccine, a company failing to meet this standard will be guilty of negligence. Any insurance beyond this level should be paid for by the government. In fact, since the Reyes decision, Congress itself has opted for this solution. In 1976, Congress passed the Swine Flu Act. This Act allowed a cause of action for all injuries and death resulting from inoculation with swine vaccine only against the United States. Under the statute, the cause of action could be brought on a theory of strict liability, negligence, or breach of warranty. The government could recoup its losses to individual plaintiffs by bringing suit against the manufacturer of the vaccine but only if that manufacturer was negligent or breached its contract with the United States by failing to meet the

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FDA standards. The government agreed to provide this insurance not necessarily because it subscribed to the view that manufacturers should be shielded from tort liability but because it had no choice. These companies, unable to obtain insurance for the swine flu vaccine, simply refused to produce the swine flu vaccine unless the government gave them this guarantee.

Similarly, Congress passed the National Childhood Vaccine Injury Act of 1986 to encourage reluctant companies to develop and market child vaccines. Like the Swine Flu Act, the 1986 legislation, which overruled the Reyes decision, reduced the potential liability exposure of vaccine manufacturers. The Act created an insurance system to compensate all victims of the covered vaccines, irregardless of any negligence on the part of a manufacturer. To fund the program, Congress passed the Omnibus Budget Reconciliation Act of 1987, which levied an excise tax on all sales of the vaccines. Under the system, if a vaccine injures a child in a specified manner, and the government cannot rebut the presumption that the vaccine caused the injury, the plaintiff receives compensation (assuming certain time requirements are met). If unsatisfied with his or her recovery from the fund, the plaintiff is allowed to sue the manufacturer. The company, however, can only be held liable if its products fell below the FDA-approved standards or if it knowingly had deceived the Agency.

Which of the above solutions to the problem of manufacturer liability is superior? It all depends on the circumstances. If a manufacturer is willing to sell a vaccine despite the addition of an excise tax, then a system similar to the one enacted by the National Childhood Vaccine Injury Act seems better. After all, such a system is less costly to the government since it does not pay for the insurance scheme. If, on the other hand, the excise tax **imposed** on the sales of a particular vaccine is large enough to deter the manufacturer from developing and marketing it, then a system similar to the one enacted by the Swine Flu Act should be tried.

Unless sale of a particular vaccine presents little chance of significant tort liability for a manufacturer, however, both solutions seem better than the one provided by the Reyes court. If designed correctly, neither of these insurance systems will provide too much disincentive to product innovation. And both provide at least a partial answer to critics who believe that strict tort liability is necessary in the event the FDA fails. Although neither system punishes the vaccine manufacturers, they do provide coverage for their victims. Most importantly, though, both provide manufacturers with notice of their liability exposure.

Nevertheless, these systems have many detractors. The two most common criticisms of government-managed insurance is its cost (only applicable to the swine flu system) and a fear that its provision will impact negatively on industry behavior. Concerning the former complaint, opponents of large government will argue that these programs are too costly. In an age of large deficits, they maintain, we simply cannot afford to provide such an insurance fund. They seem to forget, however, that vaccines have and will continue to prevent thousands of disabling injuries. It is surely better for the government to soak up the costs of vaccine development now than to pay expensive medical bills later. And, this fear of huge future costs is not ill-founded considering that millions of Americans have no health insurance and millions more have only minimal coverage.

With regard to the second complaint, proponents of tort liability believe that companies will take advantage of this insurance by not making their products safer even when doing so is possible at minimal cost. Knowing that government will pay for all injuries caused by their vaccines or that their liability will be limited to the cost of an excise tax, the argument continues, these companies will have no incentive to continually improve their products.

There are several responses to this argument. In the first place, contrary to popular opinion, executives of drug companies cannot all be evil people, completely oblivious to the public's welfare. Certainly, there must be some executives who occasionally make decisions that are not profit-maximizing. More importantly, though, even if the government insures a company's vaccines, that company still will not want to develop a reputation for making drugs that harm people. Consumer groups and the like will help keep these companies honest. Furthermore, it is unlikely that the knowledgeable scientists employed by the FDA in its Bureau of Biologics would be less aware of existing ways to improve a vaccine's safety than the scientists employed by the vaccine's manufacturer.

Finally, if one still fears that the vaccine industry will run amok if shielded from tort liability, an incentive system can be created that rewards companies for taking extra steps in the interest of safety. The tax system provides an instrument for such a system. If the number of injuries caused by a vaccine exceeds its manufacturer's share of the particular market, that manufacturer can be required to pay slightly higher taxes. These taxes will go directly into the government fund created for that vaccine's victims. On the other hand, companies that sell a vaccine that causes fewer injuries than would be expected based on the company's market share will receive a tax rebate. This system should have a positive influence on the behavior of vaccine manufacturers.

In conclusion, I would like to reiterate that this paper has been written with future vaccines in mind. It is true, of course, that most vaccines currently available are extremely safe and not prohibitively expensive. For the few injuries caused by these vaccines, an insurance system paid for by their manufacturers might be feasible and reasonable. The small increase in a manufacturer's cost of doing business could be offset by a similarly small increase in the price of the particular vaccine. Disincentive to create new vaccines would be minimal. But

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vaccines of the future may only become this safe if government insures them during their earliest stages of development. In this light, a government-paid system may be a necessary bridge between the riskier and safer periods of a vaccine's life.